NIOSH PPT Research to Support Action Plans for PPE for Healthcare Workers and Facial Anthropometrics Research Roadmap

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Respiratory Protection Research
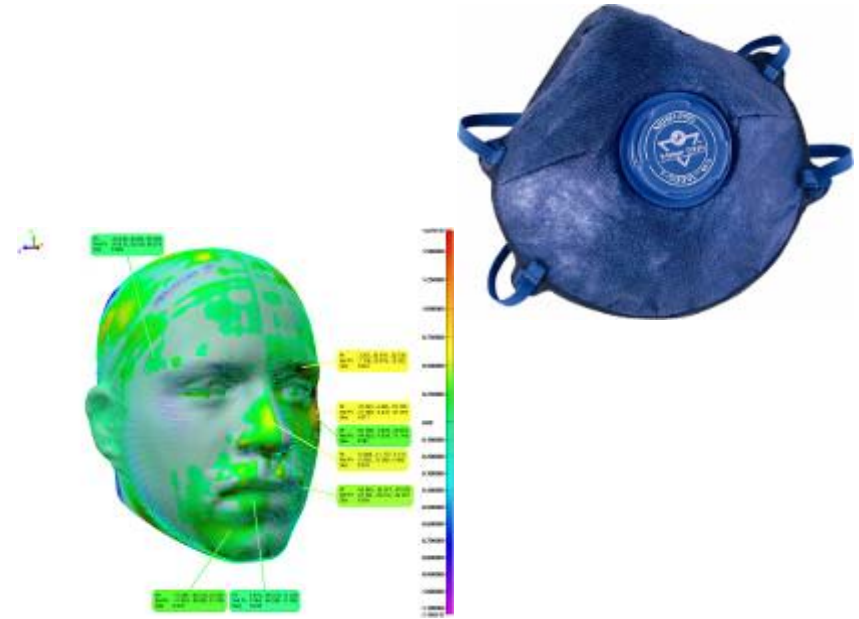
- **Influenza Pandemic**
    - FFR shortage (1, 2, 4, 5)
    - Performance (laboratory) (4, 5)

- **Respirator Fit Research**
    - Facial anthropometrics (2, 4, 5)
    - Frequency of fit testing (2)
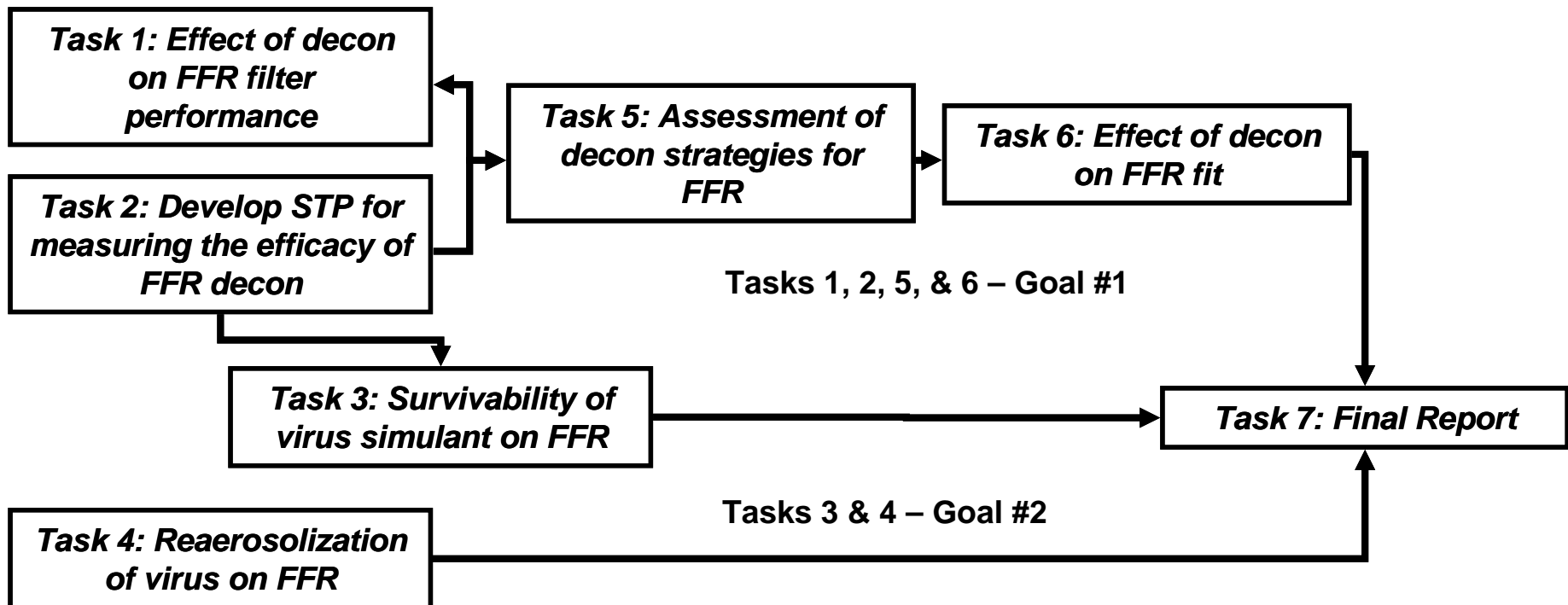   - Novel respirator designs (4, 5)

- **Aerosol/Filtration Studies**
    - Nanoparticles (4)

Assess strategies to prevent FFR shortage

Reusability of Filtering Facepiece Respirators

Goals – conduct laboratory studies to (1) understand the efficacy of decontamination and to assess the impact of decontamination on FFR performance and (2) increase the information available on the risks associated with handling a respirator exposed to viruses

Task 1: Effect of decon on FFR filter performance

Task 2: Develop STP for measuring the efficacy of FFR decon

Task 5: Assessment of decon strategies for FFR

Task 6: Effect of decon on FFR fit

Tasks 1, 2, 5, & 6 – Goal #1

Task 3: Survivability of virus simulant on FFR

Task 7: Final Report

Task 4: Reaerosolization of virus on FFR

Tasks 3 & 4 – Goal #2

Task 1. Effect of Decontamination on Filtration

- **Experimental Design**

  - 1 N95 and 1 P100 FFR model

  - Automated systems: autoclave, VHP, EtO

  - Chemical: IPA, Bleach, LHP, Soap & Water

  - Physical: UV, microwave, heat

  - Controls: water, no decon

Viscusi DJ, King WP, Shaffer RE. Effect of Decontamination on the Filtration Efficiency of Two Filtering Facepiece Respirator Models. Journal of the International Society for Respiratory Protection, (2007) 24: 93-107.
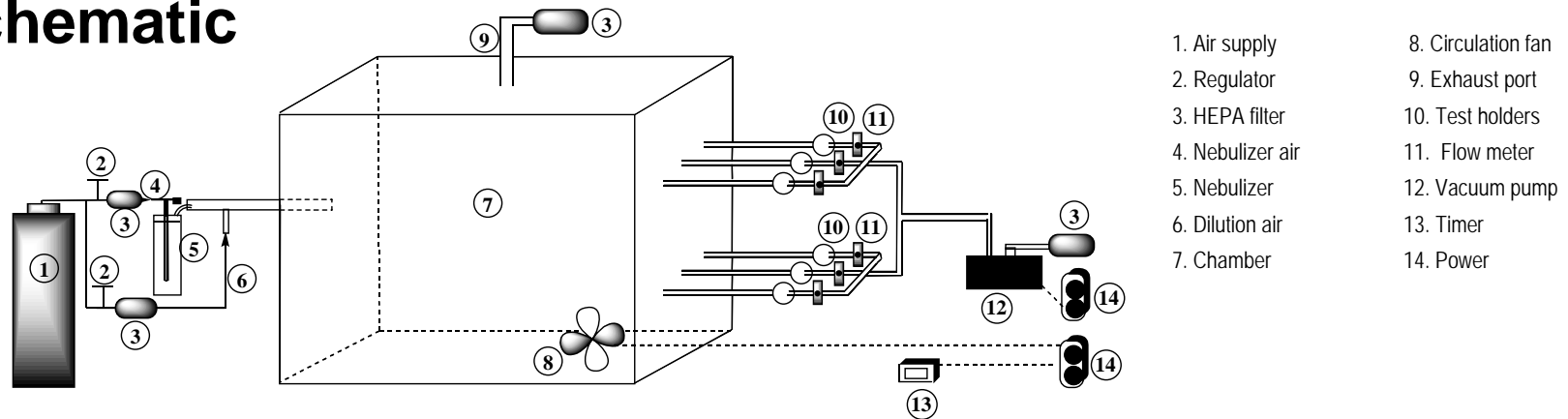
- **Preliminary Findings**

  - Autoclave, 160º C heat, 70% IPA, and soap & water caused significant filter degradation

  - Bleach, EtO, and a microwave degraded filter performance, but particle penetration levels were still less than the NIOSH certification criteria.

  - HP (vaporized and liquid forms) and UV radiation caused no significant change

  - Future research should consider low-temperature decontamination methods such as VHP/LHP, EtO, microwave radiation (< 2 min), UV, and diluted bleach.

- **Next Steps – additional FFR models**

Task 2. Bio-Aerosol Respirator Test System (BARTS)

Schematic

|	
1. Air supply	8. Circulation fan
2. Regulator	9. Exhaust port
3. HEPA filter	10. Test holders
4. Nebulizer air	11. Flow meter
5. Nebulizer	12. Vacuum pump
6. Dilution air	13. Timer
7. Chamber	14. Power

- **Validation**

  – Avg. viable MS2 recovered after 30 min loading 5.09± 0.19 log10 (RSD=4%)

  – Discriminate between varying levels of decon performance

- **Future Steps**

  – Refine draft ASTM test method

  – Study the survivability of MS2 on FFRs with and without antimicrobial technologies
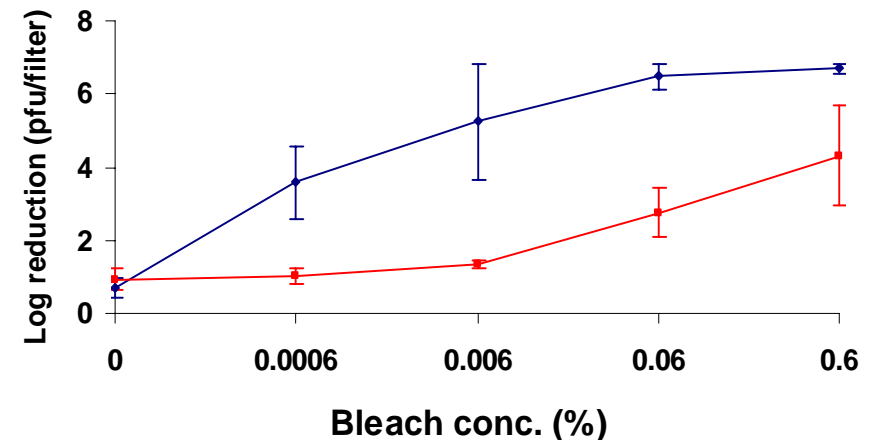
Metabolic Evaluation of N95 Respirator Use with a Surgical Mask

- **IOM recommends extending lifetime of FFR by avoiding contamination using a medical mask**

- **Physiological burden with respirator use**

  - Increased CO_2 levels speculated to cause increased frequency of headaches among health care workers

- **Does wearing a surgical mask as a protective covering over an N95 FFR increase the inhaled CO_2 concentration and breathing resistance?**

Roberge R [2008] Effect of surgical masks worn concurrently over N95 filtering facepiece respirators: extended service life versus increased user burden. Journal of Public Health Management 14(2) E19-E26.

Vojtko MR, Roberge MR, Vojtko RJ, Roberge RJ, Landsittel DP: Effect on breathing resistance of a surgical mask worn over an N95 filtering facepiece respirator. Journal of the International Society for Respiratory Protection (in press).

Metabolic Evaluation of N95 Respirator Use with a Surgical Mask

- **Approach – measure breathing resistance and O_2/CO_2 concentration inside the N95 FFR with and without the surgical mask**

    - Phase I: breathing machine and automated breathing and metabolic simulator

    - Phase II: subjects exercising on treadmill

- **Established collaboration with VA – field study on "Tolerability Assessment of Respirators in Healthcare Workers"**

- **Status – Phase I peer-review completed and data collection 25% complete. Phase II protocol under review by NIOSH Human Subjects Review Board.**

- **Goal –Complete Phase I data collection by Summer 2008. Phase II protocol data collection initiated in 2008.**
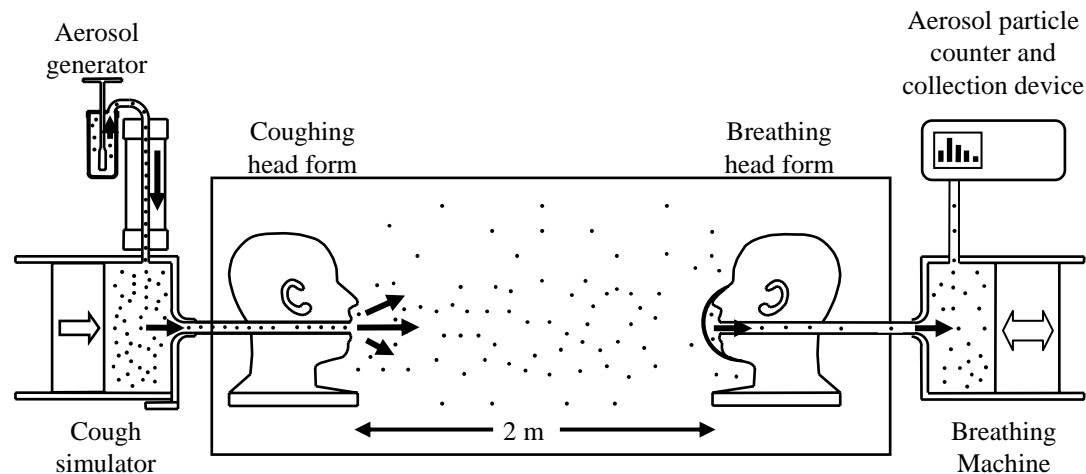
Performance

Respirator and Surgical Mask Efficacy From Cough Aerosols

- **Goal – develop an experimental system that simulates a coughing patient and a normally breathing healthcare worker**

- **Approach – examine the effects of distance on exposure, and test the efficacy of surgical masks and N95 FFRs at protecting healthcare workers from cough-generated aerosols**

- **Status – peer-review completed; Data collection is being initiated**

System Concept

Aerosol generator

Coughing head form

Breathing head form

Aerosol particle counter and collection device

Cough simulator

2 m

Breathing Machine

PAPR/N95 FFR Combination

- **Questions**

  - How much protection is provided by a loose-fitting PAPR if the motor or battery fails?

  - Any extra protection provided by wearing a fit tested N95 FFR concurrently with a loose-fitting PAPR?

- **Approach – Measured protection factors using ambient aerosol method while mounted on a mannequin and using breathing simulator**

- **Preliminary findings**

  - A protection factor of <10 is achieved if the motor/battery fails on a loose-fitting PAPR

  - 2-3 orders of magnitude greater protection if a sealed N95 FFR is used concurrently with a non-functioning PAPR

Roberge R [2008]. Evaluation of the rationale for the concurrent use of n95 filtering facepiece respirators with loose-fitting powered air-purifying respirators during aerosol-generating medical procedures. American Journal of Infection Control 36:2, 134-140.

Roberge MR, Vojtko MR, Roberge RJ, Vojtko RJ, Landsittel [2008]. Wearing an N95 respirator concurrently with a powered air-purifying respirator: Effect on protection factors. Submitted to Respiratory Care.

N95/P100 TIL Testing

- **Background – significant interest in assessing the differences in protection provided by an N95 versus P100**

- **Current concept**

    - N95 and P100 FFRs, elastomeric half-masks, and full facepiece respirators

    - Aerosols: corn oil and NaCl

    - Use new NPPTL fit test facility

- **Status**

    - Protocol in development

Project BREATHE

- **BREATHE - Better Respirator Equipment using Advanced Technology for Healthcare Employees**

- **Background**
  - Respirators on the market today were originally designed for the general needs of industrial workers and do not take into account the unique needs of the healthcare worker
  - VHA - largest integrated healthcare system in the US and uses > 1 million respirators/year

- **Concept**
  - Multi-agency working group - VHA (Champion), NIOSH, other government agencies (DoD, CDC, FDA, etc.) to develop appropriate design criteria
  - Solicit manufacturers to develop a respirator designed specifically for use by healthcare workers
  - Prototype testing done at NIOSH (laboratory) and VHA (field)

- **Current status**
  - Still in very early planning stages; MOU between VHA and NIOSH in process
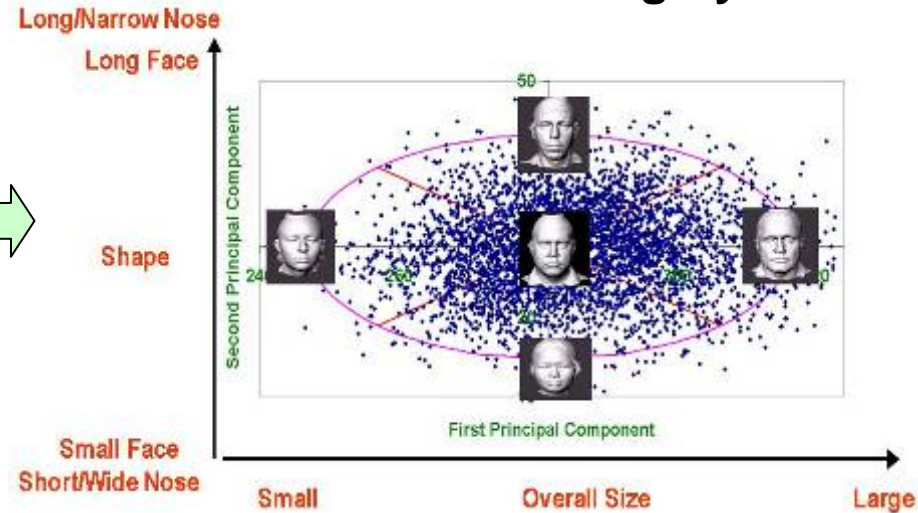 - VHA beginning to solicit members of the multi-agency working group

Respirator Fit Research

Facial Anthropometrics Research
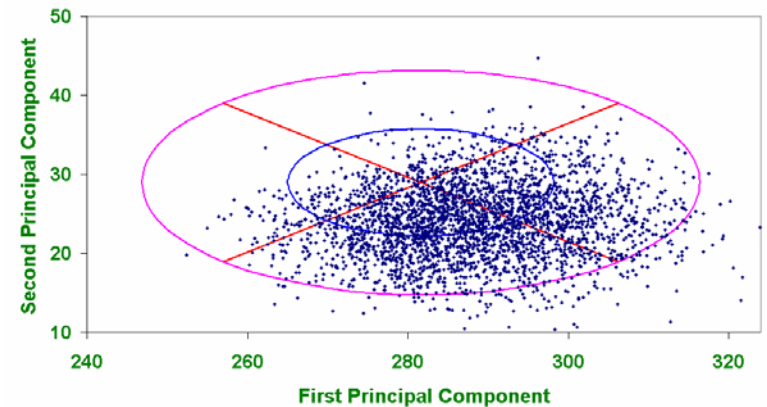
2003 Facial Anthropometrics Survey
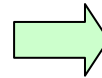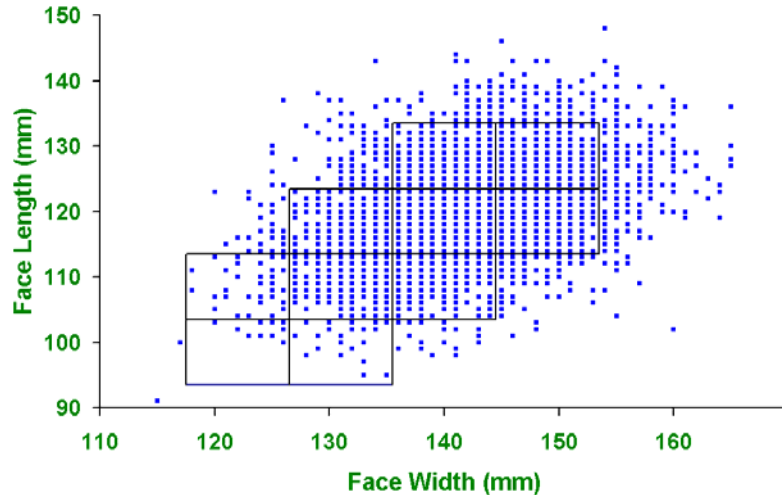
Fit Test Panels & Sizing Systems

Representative Headforms

Appropriateness of NIOSH anthropometrics data for ISO

Respirator Fit Research

- **Goal – investigate the relationships between half-facepiece respirator fit data and facial anthropometry**

- **Approach – obtained respirator fit (4 models) and anthropometric data for 30 human test subjects**

- **Current status – data collection complete, data analysis being finalized**

- **Key finding to date – correlation found between respirator size and fit test panel cells**

NIOSH face size category	Respirator size with highest passing rate	Fit Test Passing Rate		
		Respirator Size		
		Small	Medium	Large
Small (NIOSH Cells 1-3)	Small	$\frac{22}{27} = 81\%$	$\frac{18}{27} = 67\%$	$\frac{7}{27} = 26\%$
Medium (NIOSH Cells 4-7)	Medium	$\frac{32}{48} = 67\%$	$\frac{40}{48} = 83\%$	$\frac{32}{48} = 67\%$
Large (NIOSH Cells 8-10)	Large	$\frac{12}{43} = 28\%$	$\frac{33}{44} = 75\%$	$\frac{36}{42} = 86\%$

Frequency of Fit Testing

- **Background**

  - OSHA regulations (29CFR 1910.134) require respirator users to pass a fit test before using a respirator. Fit testing and training should be conducted annually

  - Factors causing changes in respirator fit are not well quantified

- **Approach – Multi-year laboratory study to investigate how changes in weight and facial shape/size affect changes in fit over time**

- **Status – protocol being revised based upon external scientific review**

- **Goal – initiate data collection in 2008**

"No-Fit-Test" Filtering-Facepiece Respirator Workshop and Research Roadmap

- **Goal – assess current state of technology available to enhance the fitting performance of negative pressure half-mask APRs and future interdisciplinary research needs and challenges in developing and certifying APRs with improved fitting characteristics**

- **Background – improving the fitting performance of respirators mentioned as a priority research need in 3 recent IOM reports**

- **Approach**

  - literature analysis to identify technologies (e.g., shape memory polymers, visual indicators) with potential to improve fitting performance

  - workshop to identify promising technologies, discuss barriers to commercialization, and to identify research gaps

  - final report which can be used to prioritize research and guide future changes to respirator certification

- **Status**

  - Contract should be awarded in March

  - One day workshop tentatively scheduled for Fall 2008

Filtration

Filtration of Nanoparticles

- **Goal – understand the effectiveness of FFRs for protection against nanoparticles**

- **Background – concerns have been raised that nanoparticles (< 100 nm) may not be captured by respirator filter media as expected by theory**

- **Approach – Measure filtration performance of N95, P100 FFRs, dust masks, and European certified FFPs using three test systems (monodisperse 4 – 30 nm, monodisperse 20 – 400 nm, and polydisperse)**

- **Key finding to date -- NIOSH certified respirators should provide expected protection levels (consistent with their APF) when used in the context of a complete respiratory program**

Silver — Sodium chloride

$R^2 = 0.8926$

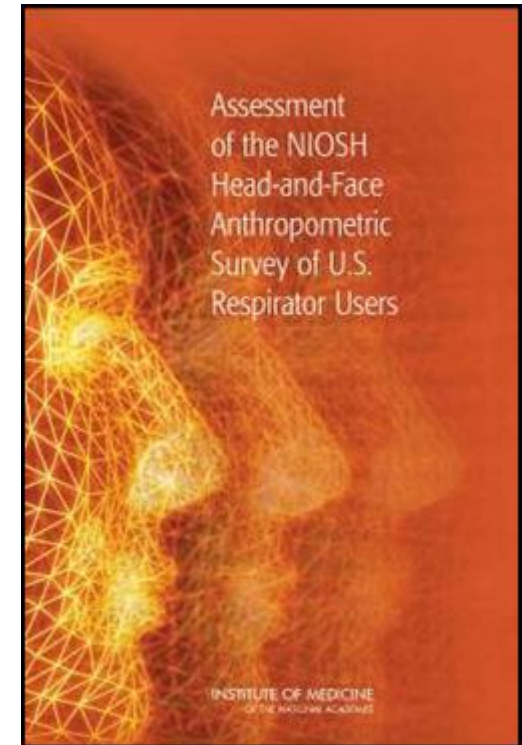Mean % Initial Penetration
Polydisperse Aerosol (TSI 8130)
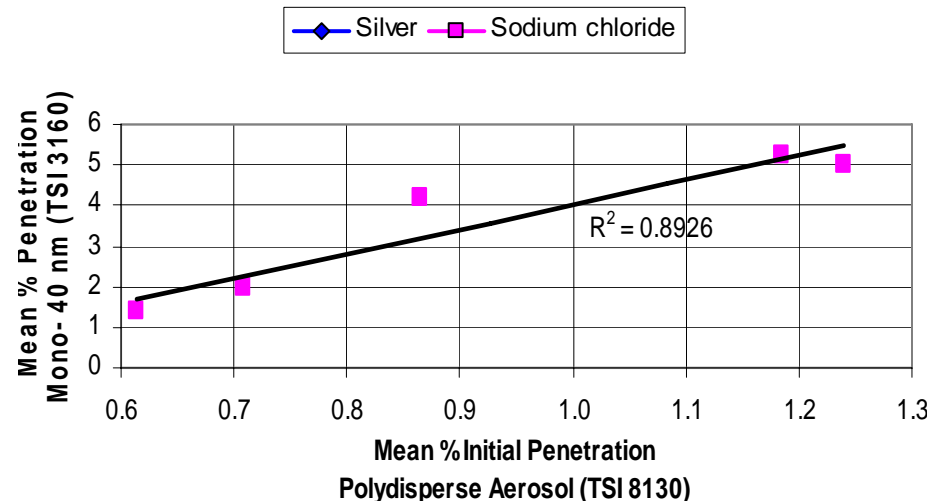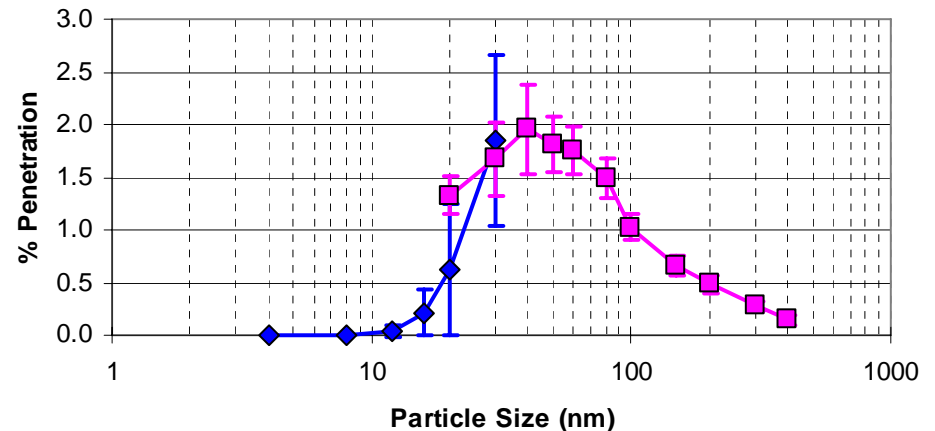
Rengasamy S, Verbofsky R, King WP and Shaffer R [2007]. Nanoparticle penetration through NIOSH-approved N95 filtering facepiece respirators. Journal of International Society for Respiratory Protection, 24:49-59.

Summary

- **NIOSH PPT program includes a diverse range of research projects addressing HCW needs identified in the IOM report**

- **New laboratory capabilities for generating well-characterized bioaerosol challenges for respirator research address unique concerns resulting from pandemic planning**

- **Outputs are being used to support NIOSH, CDC, and HHS guidance**

  - > 10 manuscripts in press, submitted, or in draft form on respirator research topics (filtration, performance, fit, decontamination)
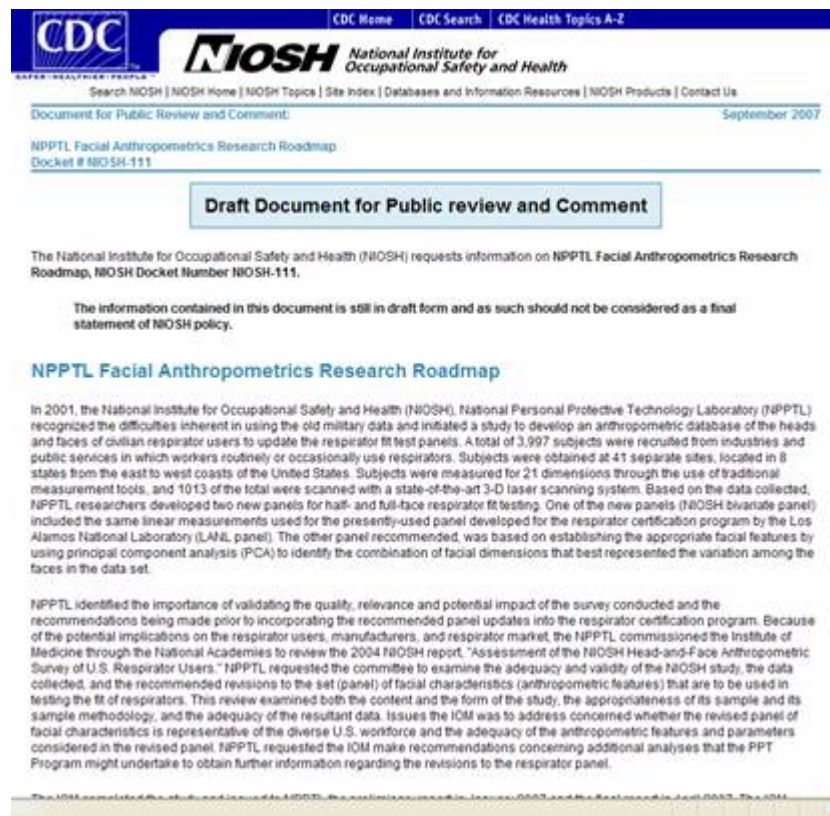
Overview - Action Plan for Facial Anthropometrics and Respirator Fit Research

- **Objective**

  - Develop a long-term strategy ("Action Plan") for facial anthropometrics and respirator fit research at NPPTL

- **Approach**

  - Analyzed IOM recommendations and reviewed on-going research in NIOSH, academia, government, and industry

- **Output**

  - Part I. NPPTL assessment of IOM recommendations

    - Detailed point by point response to each IOM recommendation.

  - Part II. Research Roadmap

    - Prioritized 10 year plan for the sequence of research projects to address information gaps


Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users

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Next steps / Implementation - Action Plan for Facial Anthropometrics and Respirator Fit Research

- **Detailed draft action plan posted to NPPTL website (September 2007)**

- **Open docket to solicit comments (September – March 2008)**

- **Revise action plan based on comments received (May 2008)**

- **Action plan will be used to prioritize selection of future NPPTL research projects, funding, staffing, and equipment needs**

http://www.cdc.gov/niosh/review/public/111/

Draft Roadmap for Facial Anthropometrics and Respirator Fit Research
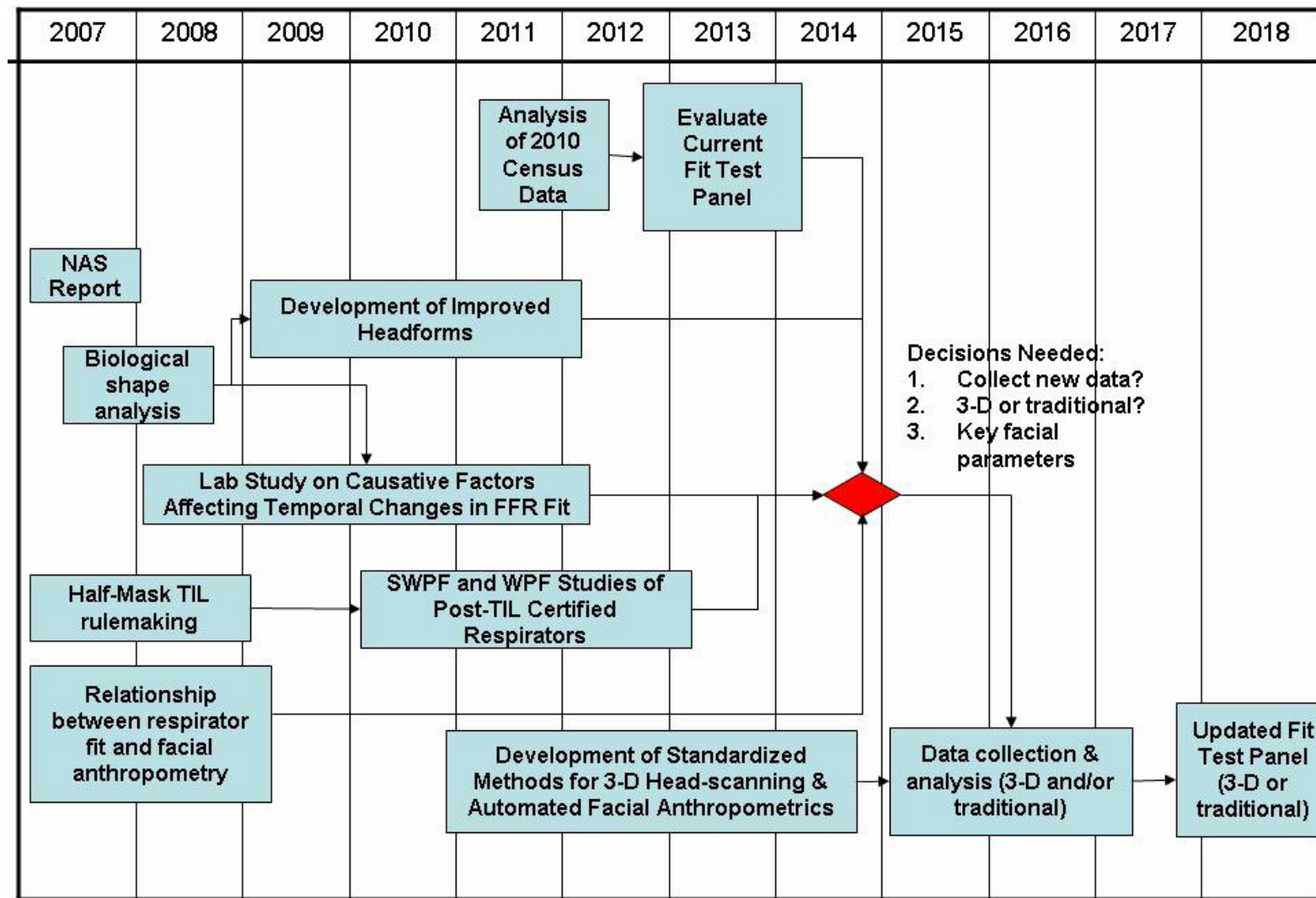
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